

Applicants: Ponnappakkam Adikesavan Loka Bharathi et al.
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REMARKS

Claims 1-5 are pending and under examination in the subject application. Claims 6-10 and 13-19 have been withdrawn. By this Amendment, applicants have amended the specification and claims 1-5. Applicants maintain that this Amendment does not introduce new matter and respectfully request entry of this Amendment.

Objections to the Specification:

The Examiner objected to the specification as reciting on page 8, lines 7-8, "International depository.....having accession no.....," and requires that on page 8, line 14, "caratenoid" be amended to its proper spelling "carotenoids".

In response, applicants note that a Second Preliminary Amendment submitted to the U.S. Patent Office on March 31, 2004 amended the specification at page 8, lines 7-8 to identify the International Depository and Accession No. of the claimed bacterium. Applicants further note that the spelling of carotenoid has been corrected by this Amendment. Accordingly, applicants maintain that the specification so amended overcomes the Examiner's ground of objection.

Objection to the claims:

The Examiner objected to claims 3 and 4 because in claim 3, line 5, the term "caratenoid" should be spelled correctly as "carotenoid" and in claim 4, line 2, "laving" should be spelled correctly as "having". Applicants note that these misspellings have been corrected by this Amendment. Accordingly, applicants maintain that claims 3 and 4 so amended overcome the Examiner's ground of objection.

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Rejection under 35 U.S.C. §101:

The Examiner rejected claims 1-5 under 35 U.S.C. 101 as allegedly directed to non-statutory subject matter. The Examiner stated that the instant claims are drawn to a deep sea bacterium found in nature and do not suggest or recite any limitations to indicate the instant bacterium is a "nonnaturally occurring manufacturer or composition of matter - a product of human ingenuity - having a distinctive name, character, [and] use" (MPEP 706.03(a)B and 2105).

In response, applicants note that claims 1-5 as amended provide for an "isolated deep-sea bacterium". Accordingly, applicants maintain that claims 1-5 so amended overcome the Examiner's ground of rejection.

Rejections under 35 U.S.C. §112, First Paragraph:

The Examiner rejected claims 1-5 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner stated that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner stated that the instant claims are drawn to a deep sea bacterium, which is identified solely by an accession number and the depth at which the bacteria was collected from the Indian Ocean, and that the specification fails to set forth any identifying taxonomic, structural, physical or functional characteristics possessed by the bacterium. The Examiner stated that while the specification states that the bacterium has

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"similar properties to *Brevibacterium casei*," the specification fails to identify what these properties are, how they are similar and/or how they differ.

The Examiner further stated that while applicants may show possession of the claimed bacterium by describing a deposit made in accordance with 37 CFR 1.801 or by reference to a deposit, such a deposit is not a substitute for a written description. The Examiner stated that the written description of the deposited material needs to be as complete as possible because the examination for patentability proceeds solely on the basis of the written description.

In response, applicants respectfully traverse the Examiner's ground of rejection.

According to M.P.E.P. §2163, an application may show actual reduction to practice in the case of biological material by specifically describing a deposit made in accordance with 37 C.F.R. §1.801 *et seq.* A "reference in the specification to a deposit may also satisfy the written description requirement with respect to the claimed material" (*Enzo Biochem*, 296 F.3d 1316, at 1329). Applicants note that on page 8 of the specification, lines 5-9, the claimed bacterium is specifically described deposited on August 19, 2003 with the Microbial Type Culture Collection and Gene Bank (MTCC), Institute of Microbial Technology, Sector 39-A, Chandigarh - 160 036, India under the provisions of the Budapest Treaty having Accession No. MTCC 5114.

In addition, applicants note that the characteristics of the isolated deep-sea bacterium are disclosed in the specification. For example, on page 8, lines 10-14, the claimed bacterium is described as baroduric and having similar characteristics of

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carotenoid compounds. On page 8, lines 16-17, a bacterial extract of the claimed bacterium is described as having carotenoid, UV absorption, anti-bacterial and pH indication properties. On page 10, lines 5-6, the bacterial extract is also described by capable of inhibiting growth of both Gram-positive and Gram-negative bacteria. On page 10, lines 8-10, the bacterial extract is also described as capable of reversible color change, being pink under alkaline conditions and yellow under neutral or acidic conditions. Accordingly, applicants maintain that the properly identified deposit of the claimed bacterium and its disclosed characteristic in the specification provide adequate written description.

The Examiner also rejected claims 1-5 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner stated that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner stated that claims 1-5 are drawn to a deep sea bacterium, disclosed as a deep sea bacteria found in the coastal zone of Arabian Sea, Goa, India with properties similar to *Brevibacterium casei*. However, the specification does not disclose a repeatable process to obtain the microorganism required and it is not apparent if the microorganism is readily available to the public. The Examiner alleged that applicant does not describe any taxonomic, structural, physical or functional characteristics possessed by the specific bacterium that is claimed designated. Moreover, the Examiner alleges that the generic statement, "which has a similar properties to known *Brevibacterium casei*" without more, does not provide the

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identifying characteristics of the bacterium or an extract thereof. The Examiner stated that absent such teachings and guidance as to the identifying characteristics of the bacterium, or of the petroleum and alcoholic extracts thereof, the specification is lacking critical information which would enable one skilled in the art to prepare, reproducibly and consistently, make or use the invention. The Examiner alleges that the specification does not provide information by which one can identify the bacteria to be extracted to obtain the claimed composition.

The Examiner stated that since the microorganism is recited in the claims, it is essential to the invention recited in those claims, and must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The Examiner stated that if the microorganism is not so obtainable or available, a deposit of the microorganism may satisfy the requirements of 35 U.S.C. § 112.

The Examiner stated that it appears a deposit was made in this application as filed as noted on page 8 of the specification. However, it is unclear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. The Examiner also stated that applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C. § 112, first paragraph, by stating that the deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

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Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

In response, applicants respectfully traverse the Examiner's ground of rejection.

As stated above, on page 8 of the specification, lines 5-9, the claimed bacterium is specifically described deposited on August 19, 2003 with the Microbial Type Culture Collection and Gene Bank (MTCC), Institute of Microbial Technology, Sector 39-A, Chandigarh - 160 036, India under the provisions of the Budapest Treaty having Accession No. MTCC 5114. Applicants note that the specification discloses the process for preparing the bacterial extract of the deposited bacterium at page 11, lines 19-28. Furthermore, applicants note that Table 3 on page 15 of the specification discloses the characteristics of *Brevibacterium casei* which are similar to the claimed deep-sea bacterium. Accordingly, applicants maintain that the specification enables one skilled in the art to use the claimed invention.

Applicants maintain that in light of the remarks above, the specification of the subject application satisfies both the written description and enablement requirements of 35 U.S.C. §112, first paragraph, and request that the Examiner reconsider and withdraw these grounds of rejection.

Rejections under 35 U.S.C. §112, Second Paragraph:

The Examiner rejected claims 1-5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants

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regard as the invention. The Examiner stated that although the claims recite a depository accession number, neither the claim language nor specification set forth an adequate description or definition of the scope of the invention in such a way that it is clear what bacterium is being claimed. Specifically, the Examiner stated that claim 1 and its dependents are rendered vague and indefinite for reciting "Type Culture Collection and Gene Bank" because it is unclear if applicant intends the phrase to read "Microbial Collection and Gene Bank", as this appears to be the actual name of the depository MTCC. The Examiner also stated that claim 1 and its dependents are drawn to a bacterium, however are rendered vague and indefinite because it is unclear if the claimed bacteria is isolated from the deep sea at 5000m, or if *B. casei* is isolated from the deep sea at 5000m. The Examiner also stated that the claims are further indefinite for reciting "similar properties to known *Brevibacterium casei*" because the claim language and specification fail to define what "similar properties" exist, or what the properties are. The Examiner also stated that claim 2 is confusing for reciting "on i.e. it" because it is unclear if the phrase that follows is intended as a further limitation. Furthermore, the Examiner stated that in claim 3, lines 2 and 5, "the petroleum ether fraction" and "the carotenoid compound" lacks sufficient antecedent basis; and in claim 4, line 2 "the alcoholic extract" lacks sufficient antecedent basis. The Examiner further stated that claim 4 is rendered indefinite because it is unclear if the disclosed properties are of the bacteria itself or of an extract of the bacteria. Moreover, the Examiner stated that it is unclear if the claim is to (a) an alcoholic extract of a bacteria, or (b) to a bacteria whose alcoholic extracts has the claimed properties. The Examiner further stated that in claim 5, line 2, "the extract" lacks sufficient antecedent basis and that claim 5 is rendered vague and indefinite for reciting "many

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industrial applications" because the claim language or specification fail to adequately define what the "many industrial application" include or exclude. The Examiner further stated that claim 5 is indefinite for reciting "such as" because it is unclear whether the limitations following the phrase are part of the claimed invention and for reciting "colour cum preservative" because the phrase is not adequately defined by the claim language or specification.

In response, applicants note that claims 1-5 have been amended to address the Examiner's concerns and more clearly define the claimed invention. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw these grounds of rejection.

Rejections under 35 U.S.C. §102(b) :

The Examiner rejected claims 1-5 under 35 U.S.C. 102(b) as allegedly unpatentable over Funke et al. (1996). Specifically, the Examiner stated that applicants claim a deep sea bacterium with similar properties to *Brevibacterium casei*.

The Examiner stated that Funke teaches *Brevibacterium casei* bacteria, defined in 1983, and various properties of the bacterium

The Examiner stated that since applicants specifically state that the bacterium of the invention has similar properties to that of *B. casei*, and does not provide any other properties to the claimed bacterium, the strains appear to be the same. The Examiner therefore stated that, while Funke does not teach that the bacterium is baroduric or that extracts of *B. casei* exhibit the claimed properties, such properties would be intrinsic to the

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disclosed bacteria. The Examiner also stated that although Funke does not teach that the bacterium can be used in the manner instantly claimed, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. The Examiner stated that in order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. The Examiner stated that in the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting.

Finally the Examiner stated that the Funke reference discloses a strain that appears to be identical to the presently claimed strain, and, consequently, the claimed strain appears to be anticipated by the aforementioned reference.

In response, applicants respectfully traverse the Examiner's ground of rejection.

According to M.P.E.P. §2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Applicants maintain that Funke et al. fail to teach each and every element of the deep-sea bacterium as claimed.

Amended claim 1 provide for an "isolated deep-sea bacterium deposited with the National Institute of Oceanography, Goa, India, having accession no. NIOCC isolate #222, and deposited with the Microbial Collection and Gene Bank (MTCC) having accession no. MTCC 5114, which isolated deep-sea bacterium was isolated from the deep sea at 5000m depth waters of the Indian Ocean." Amended claim 2 further provides that the bacterium of claim 1 is baroduric. Amended claim 3 provides that a petroleum

ether fraction of the bacterium of claim 1 has similar characteristic peaks as a carotenoid compound. Amended claim 4 provides that an alcoholic extract of the deep-sea bacterium of claim 1 has carotenoid, UV absorption, anti bacterial, and pH indicating properties. Amended claim 5 provides that the extract of claim 4 may be used as a food and beverage additive and preservative. Applicants maintain that the claimed deep-sea bacterium is not *B. casei*. Funke et al. teach that *B. casei* was defined in 1983, and found to be the prominent strain of *Brevibacterium* isolated in clinical specimens. Funke et al. does not teach a deep-sea bacterium isolated from the Indian Ocean at 5000m water depths. Furthermore, as the Examiner stated Funke does not teach that the bacterium is baroduric or that extracts of *B. casei* exhibit the claimed properties. As detailed in Table 3 on page 15 of the specification, the properties which are similar to *B. casei* are color, anti-bacterial property, and UV absorption property. *B. casei* is not a deep-sea bacterium found at 500m water depths of the Indian Ocean. It is well known in the art, since 1983 as disclosed in Funke et al., that *B. casei* belongs to a bacterial genus found as normal human skin flora and in raw milk and on the surface of cheeses. Accordingly, applicants maintain that Funke et al. do not teach each and every element of any of claims 1-5.

The Examiner also rejected claims 1-5 are rejected under 35 U.S.C. 102(b) as allegedly unpatentable by Rozzell, Jr. (US 5885767 A). Specifically, the Examiner stated that Rozzell teaches a deposited *Brevibacterium casei* bacterium and various properties thereof (col.13).

The Examiner stated that since applicant specifically states that the bacterium of the invention has similar properties to that of *B. casei*, and does not provide any other properties to the

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claimed bacterium, the strains appear to be the same. Therefore, the Examiner stated that while Rozzell does not teach that the bacterium is baroduric or that extracts of *B. casei* exhibit the claimed properties, such properties would be intrinsic to the disclosed bacteria. The Examiner therefore concludes that the reference discloses a strain that appears to be identical to the presently claimed strain, and, consequently, the claimed strain appears to be anticipated by the aforementioned reference.

In response, applicants respectfully traverse the Examiner's ground of rejection.

Applicants again maintain that the claimed deep-sea bacterium is not *B. casei*. Rozzell et al. do not teach a deep-sea bacterium isolated from the Indian Ocean at 5000m water depths. Furthermore, as the Examiner stated Rozzell does not teach that the bacterium is baroduric or that extracts of *B. casei* exhibit the claimed properties. As stated above, the disclosed properties which are similar to *B. casei* are color, anti-bacterial property, and UV absorption property. Accordingly, applicants maintain that Rozzell et al. do not teach each and every element of any of claims 1-5.

Applicants maintain that in light of the remarks above, amended claims 1-5 satisfy the requirements of 35 U.S.C. §102(b), and request that the Examiner reconsider and withdraw these grounds of rejection.

Conclusion

In light of the arguments above, applicants maintain claims 1-5 as amended address the Examiner's concerns and obviate the grounds of rejection set forth, and solicit allowance of the

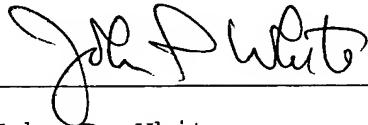
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pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the telephone number provided below.

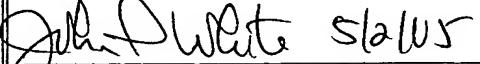
No fee, other than the \$450 extension fee, is deemed necessary in connection with the filing of this Amendment. However, if any other fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450


John P. White Date
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